SUPPORTING STATEMENT
IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD
OMB Control No. 0910-0186

A. Justification

1. Necessity for the Information Collection

Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s) (Attachment A) and 21 U.S.C. 348 (Attachment B)), food irradiation is subject to regulation under the food additive premarket approval provisions. The regulations providing for uses of irradiation in the production, processing, and handling of food are found in part 179 (21 CFR part 179). To ensure safe use of a radiation source, § 179.21(b)(1) requires that the label of sources bear appropriate and accurate information identifying the source of radiation and the maximum energy of radiation emitted by x ray tube sources. Section 179.21(b)(2)(i) requires that the label or accompanying labeling bear adequate directions for installation and use. Section 179.25(e) (Attachment C) requires that food processors who treat food with radiation make and retain, for 1 year past the expected shelf life of the products up to a maximum of 3 years, specified records relating to the irradiation process (e.g., the food treated, lot identification, scheduled process, etc.). The records required by § 179.25(e) are necessary because they are used by FDA inspectors to assess compliance with the regulation that establishes limits within which radiation may be safely used to treat food. The agency cannot ensure safe use without a method to assess compliance with the dose limits, and there are no practicable methods for analyzing most foods to determine whether they have been treated with ionizing radiation and are within the limitations set forth in part 179. Records inspection is the only way to determine whether food processors are complying with the regulations for treatment of foods with ionizing radiation.

The Food and Drug Administration requests continued OMB approval for the information collection requirements contained in the following:

21 CFR 179.25(e) - Recordkeeping

Requires maintenance of records in irradiation treatment of foods.

2. Uses of the Information

As discussed above, the information is used by FDA during establishment inspections to assess compliance with regulations that establish limits within which radiation may be safely used to treat food. The agency cannot ensure safe use without a method to assess compliance with the dose limits, and there are no practicable methods for analyzing most

foods to determine if they have been treated with ionizing radiation and are within the limitations set forth in 21 CFR part 179. Records inspection is the only way to determine whether food processors are complying with the regulations for treatment of foods with ionizing radiation. Thus, the purpose of the information collection is to permit assessment of the firm's compliance with the agency's regulations.

3. **Use of Improved Information Technology**

The regulation does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. Food processors are free to use whatever forms of information technology may best assist them in retaining the appropriate records and making them available to regulatory officials.

4. **Efforts to Avoid Duplication and Unavailability of Similar Information**

There is no duplication at the federal level because no other federal agency requires food processors to retain these records.

5. **Methods to Minimize Burden on Small Businesses**

A limited number of firms process food using irradiation. The recordkeeping requirements are no more burdensome for small businesses than for large, and such records would ordinarily be kept by these food processors for their own use as a matter of good management procedures. Consumer Safety Officers in the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, at FDA are available by telephone to answer any questions about recordkeeping requirements.

6. **Consequences if Data Were Collected Less Frequently**

If the recordkeeping requirements were not met by the food processor, FDA would, in most cases, be unable to verify that the food has been processed in accordance with applicable regulations.

7. **Special Circumstances**

None of the requirements are inconsistent with the guidelines in 5 CFR 1320.5.

8. **Outside Consultation**

In the Federal Register of February 6, 2006 (71 FR 6075), FDA published a 60-day notice requesting public comment on the information collection provisions (Attachment D). FDA received one letter in response, which contained several comments and

suggestions. These suggestions and FDA's responses follow. The comment expresses concern that records maintained under the regulation must only be retained for a maximum of three years. The comment asserts that irradiation of food is a new process, the long term effects of which are unknown. The comment recommends that the required records be retained for seven years. FDA disagrees. The records required by § 179.25(e) must be retained for a period of time that exceeds the shelf life of the irradiated food product by 1 year, up to a maximum of 3 years, whichever period is shorter. There is no need to retain the information longer than 1 year after the end of the shelf life of the irradiated food because by that time the food has either been consumed or discarded. Thus, it is unnecessary for FDA to require firms to retain the records for a longer period of time. The comment also suggested that FDA permit comments to the docket to be filed by e-mail and suggested that food treated pursuant to part 179 of the regulations should be labeled with the word, "Irradiated." FDA agrees that irradiated food should be labeled and notes that labeling requirements for irradiated foods are found at 21 CFR 179.26(c). These comments are outside the scope of the four collection of information topics on which the notice solicits comments and, thus, will not be addressed further.

9. Payment or Gifts

No payment or gifts are offered to respondents for fulfilling their obligation to retain the appropriate records and make them available to regulatory officials.

10. Confidentiality

Information that is trade secret or confidential is subject to FDA's regulations on the release of information, 21 CFR Part 20. To the extent 21 CFR 20.64 applies, the FDA will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

11. Sensitive Questions

This information collection does not involve any questions of a sensitive nature.

12. Estimate of Burden

FDA estimates the total hour burden for this information collection to be 720 hours, as follows:

Estimated Annual Recordkeeping Burden[1]					
CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
179.25(e)	6	120	720	1	720

1 There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of firms who process food using irradiation is extremely limited. FDA estimates that there are two irradiation plants whose business is devoted primarily (i.e., approximately 100 percent) to irradiation of food and other agricultural products. Four other firms also irradiate small quantities of food. FDA estimates that this irradiation accounts for no more than 10 percent of the business for each of these firms. Based on discussions with a representative of the industry, we estimate that the recordkeeping burden for a facility that is primarily devoted to food irradiation would be one hour per day for 300 days, for a total of 300 hours per year, and the recordkeeping burden for a facility that devotes only 10 percent of its business to irradiation would be approximately 30 hours per year. Thus, the total burden hours may be calculated as follows for two facilities primarily devoted to food irradiation and four facilities devoting only 10 percent of their business to food irradiation: 2 x 300 hours plus 4 x 30 hours, or 720 hours annually.

No burden has been estimated for the labeling requirements in§§ 179.21(b)(2)(i) and (b)(2)(ii) and 179.26(c) because the information to be disclosed is information that has been supplied by FDA. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information.

Estimated Annualized Cost for the Burden Hours.

The cost of the recordkeeping requirement to irradiation facilities is minimized because the recordkeeping requirement reflects customary business practice. FDA estimates that the cost for the retention and disclosure of records for food products under this regulation would equal approximately $17,308.80. In this calculation of cost, FDA estimates that the average hourly cost for retaining the records and making them available to regulatory officials would be $12.02 per hour. Total annual burden hours (720) multiplied by $12.02 per hour equals $8,654.40. To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondents $17,308.80.

13. Costs to the Respondent

There are no capital costs or operating and maintenance costs associated with this collection.

14. Cost to the Federal Government

FDA's review of the retained records would generally occur as part of its routine establishment inspection activities. FDA would devote approximately 5 hours per inspection to the inspection of records. FDA estimates the annualized cost to the Federal Government for the review of records retained by a firm to be $315.40 per review. In this calculation of cost, FDA estimates the hourly cost for review and evaluation at a base GS-13, step 1 salary of $31.54 per hour. Five hours multiplied by

$31.54 per hour equals $157.70. To account for overhead, this cost is increased by 100 percent, making the total annualized cost to the Federal Government $315.40 per review.

15. **Changes or Adjustments in Burden**

There has been no change in the burden.

16. Statistical Analysis, Publication Plans, and Schedule

There are no plans to publish data from this information collection.

17. Approval Not to Display Expiration Dates

No approval requested.

18. Exception to Certification Statement

No exceptions requested.

B. Collections of Information Employing Statistical Methods

This collection of information does not employ statistical methods.